HUMAN TESTING OF PESTICIDES: DEBATES AND ETHICAL ISSUES

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ABSTRACT

The introduction of new technology requires testing. But the question is do we consider humans as expendable resources? Tests are conducted in human subjects for decades; some tests are called clinical trials, others are toxicologic studies (Toxicity profile). Can we really see the difference? Toxicity, as well documented by toxicologists is dose-dependent. One dose can be theraputic, another dose of the same chemical can be lethal. Laws and regulations can not deter researcher and manufatureres from using human suibjects, even in the higly advanced countries,*i.e*. USA, England, and Scotland. Conflicts of interests , and need for grants forced the concerned organization to issue permissive and weak protocols. Debates , inter- and intra- organizations, are going on, and will continue forever, between cons and pros. The result in our openion will be at the end is to find a suitable and soft wording for the issue, *i.e***. YES,** humans are expendable resources.

INTRODUCTION

The introduction of a new technology requires testing by conducting a carefully managed learning process, with two main functions:

a) **An operational function**, to discern whether the new product or process can efficiently provide anticipated benefits and **safety function** to identify its risks, which may be latent, and unknown at the outset, and
b) To determine if these **risks** are **manageable**.

Experience indicates that the safety function is **vulnerable** to deliberate or inadvertent **compromise** when it is managed by proponents of the technology, who are striving to achieve results which promise personal or organizational **gain**. Compounding the problem is the multiplicity of individuals, and organizations commonly involved in such trials, making it a **multi-party enterprise** in which coordination, and communication difficulties may arise, and cause responsibilities to become diffuse, and uncertain. Moreover, urgency and pressure for success, because of the **substantial investment** of capital, facilities, and human resources, over the long period of time usually involved in bringing advances to the market, are **making the issue more complex**.

In our interests to hasten development of new technology products, we have created a vast **interprise** of **clincal trials** in which experimentation on **thousands** of human subjects is performed

without sufficient regard for their safety, and without reasonable prospects for their theraputic benefits.

We claim that trials are governed by **ethics**, and that **informed consent** serves as the primary safeguard for human subjects. Agencies, Environmental Protecion Agency (**EPA**), National Institutes of Health (**NIH**), and others in USA, **avoid** setting **explicit limits** on the risks of human experimentation, to tolerate their **financial** conflicts of interest, which can have a deleterious effect on essential **precautionary** attitudes, and procedures, and to accept claims that **violations** of research **protocols**, and the harms suffered by human subjects constitute **proprietary informaion**, which must be kept **confdential** in order to protect **trade secrets**, and potentially pattentable subject matter. Relying on institutional review boards to hold risks in check is inadequate. **Incoherent** and **confusing** array of rules, exemptions, and ambiguous guidelines for conducting trials safely, provide grounds for violations. Arbitrary inforcement system, which neither deters researchers, managers and sponsors from **violation**, nor holds them **accountable**.

The result is that we tolerate a **multitude of harms** to human beings, most of which have not even duly reported. Thus, we drifted away from traditional regard for **safeguarding** humans in the process of testing, and advancing a new technology. Hence, a responsible **corrective course** needs to be charted. **Humans** are viewed as **expendable resources**!!

Toxicological studies in which the " *Test animals are people*" have recently been conducted by several major **pesticide manufactureres**. The Environmental Working Group (**EWG**), in Washington D.C., which is a research and academic organization, reported that: *Most of the recent experiments have been performed in England and Scotland, eventhough, the pesticides may be made by firms headquartered elsewhere*. The EWG cited three experiments conducted in 1997 in **England**, for **Avmec Chemical Corp**. (California, USA), in which volunteers drank small amounts of the organophosphate **dichlorvos** (nerve poison, synaptic derivative, AchE inhibitor), mixed into corn oil.

In 1992, **Rhone-Poulenc** (French), paid volunteers in **Scotland** to drink orange juice that had been spiked with the **oxime** carbamate **aldicarb** (neurotoxicant, AchE inhibitor, LD50<1 mg/kg body weight).

Some subjects experienced **adverse symptoms**, and showed evidence of toxicity, *i.e.* inhibition of ChE. EWG noted that "**EPA** confirmed that additional human toxiclogy studies are **underway overseas**".

Industry believes human testing data could **disprove** some of the harmful risks associated with pesticde. Environmental groups believe that "*If human teting is used by EPA, there would be less of a reason to get rid of the pesticides*". EPA reported to support the use of human testing data to regulate pesticides. EPA requested the report from A Scientific Advisory Panel, that it established to **weigh** the **scientific**, **ethical**, and **political** implications of human testing.

Clinical trials provide much of the data used by the Food and Drug Adminstration (**FDA**) to determine whether the **products** are suitable for **routine use** in health care. This is of obvious importance to **medical progress** and improvement of public health, and those who have career and **financial** interests at stake. BUT, are also important to the human subjects involved, because the products being tested on them may remedy their illnesses, but may also pose RISKS, since the products have usually not been **previously** tested on humans. The clinical trial is a point at which **research** and **practice** of medicine intersect. It is supposed to be designed and managed to achieve dual societal objectives:

1. The generation of **clinical evidence** regarding the **efficacy** and **safety** of new products, and
2. The **responsible application** of such products to select human subjects for potential theraputic benefits.

   The **IND** (Invesigating New Drug), with the approval of FDA, for conventional drugs, has an important safety assurance, *i.e.* **toxicity profile** with data showing that human **metabolic processes** will safely accommodate and breakdown the test substances.

   Activity of some biologic products is highly **species-specific**, *i.e. animal doses do not always extrapolate linearly to human doses.* Clinical trials may involve many subjects, take place at scattered sites in several countries, and are increasingly done by **obscure** "contract research organizations" for companies **sponsoring** the trials. Therefore, mangement for full compliance with requisites, and protocols is a **formidable task**.

   Pesticdes manufactureres argument is:

   1. U.S. regulating **limits** for specific pesticide **residues** in foods, derived from animal data, are set **too high**,
   2. No Observable Adverse Effect Level (**NOAEL**) studies are VITAL to **accurately** establish risk,
   3. Industry conducted human studies "do not endanger subjects", and results are NEEDED to enhance information obtained from testing on animals.

   Although the U.S. law prohobits the type of studies to be occurring overseas, it has **not** prohibited **use** of data from them.

EPA (1998) noted "We are deeply concerned that some pesticide manufactureres seem to be engaging in **health-effects studies** on human subjects" as a way to avoid the agency employing a safety factor for applying results of animal tests to people. EPA also stated that "Protection of public health from adverse effects of pesticides can be achieved through reliance on animal testing, and use of the **highest ethical standards**.

American Crop Protection Association (ACPA) stated the following:

1.**You can not draw line**, because human testing is always **valuable**. It is ethically wrong not to use all of the data,
2.Human tests are **safe**, and
3.The compounds studied are widely found in small concentrations in the **environment** and **food supply**.

Human tests flourished in the 1960's and 1970's. Concerns about **ethics** and **safety** led most companies to discontinue such tests. Attempting to show that their products are safe, large makers **resumed testing** their pesticides on people to aid in the government's risk assessment. The argument is : *Human studies are **more accurate** than animal studies, and might establish a higher safe dose* (only the a.i.).

In May 1998, EPA published a **Fedral Notice** that human tests might be **helpful** in assessing safety risks. When a criticism of the notice surfaced, th EPA set up a Special Advisory Panel to recommend **a refined policy** that considers the **safety**, **ethics** and **conditions** of human test. In November, the advisory panel, in a bakground paper of the agency stated that : The agency **accepts** other human tests, *e.g*. those studying people who apply pesticides on fields, and for buisinesses. EPA said that the 1996 law " *may have **unintentionally** created an **incentive**" to test pesticides in human volunteers. These studies raise difficult scienfic and ethical questions. We are **not yet able to answer**, and we are **deeply concerned** about them.*

Researchers in 1999 asked volunteers in **Nebraska** (USA) to swallow small doses of a.i. to examine its potential harmful effects on people. The study was one of 14 submitted to EPA that involve people ingesting 10 different pesticides. The 13 other studies were on volunteers in the **U.K**. Together, the studies are at the heart of a debate among scientists, ethicists, and pesticide makers about the scientific value, the standards for, and the moral justification of testing pesticides (only a.i.) on humans. Some at the EPA, which regulates pesticides, see **clear value** in these human studies; many do not. There are many people at the agency who are **troubled** by

the fact this testing has ever gone on, and is going on, or might ever go in the future.

For the **MDS Harris research**, some of the 60 volunteers swallowed a capsule containing chlorpyrifos. Some of the 60 volunteers were part of the control group, and were given placebo. The volunteers earned **$460** for their participation. The participants in Great Britan are paid twice as much. The compound can disrupt the nervous system. The supporters stated that: *It is hoped that the tests will show how much of the a.i. can be ingested without any* ***noticeable*** *harm to people.* Doses given to volunteers fell well under a toxic dose. The results of the test were as follows: Volunteers reported developing one incident each of nausea, vomiting, abdominal pain, shortness of breath, impairment of sensation, and chest pain.

A spokesman for DOW (the manufacturer; G. Smith) said:

1. DOW sought the human research to add to 3,600 previous research studies, and reports on the pesticides (lab., animal research, and studies of people who apply or work in areas in which chlorpyrifos is applied).
2. Direct testing on human volunteers can help **clear up uncertainty** that exists between animal studies and the eventual impact on people.

President of EWG asked two questions:

1. Would you want your child to participate in a study like this?
2. What good does it do to only test the a.i. when you are using/inquiring all of the "inert", contaminants, metabolites, and any/all synergestic effects?

In 1996, U.S. Congress passed The Food Quality Protection Act, which required stricter protections for **children** from pesticides.

The pesticide makers compare the pesticide studies to what are called **Phase I clinical drug test** commonly submitted to the use of FDA. In those tests, the objective is to determine **adverse reaction levels** to a drug. Bioethicists and EPA panel members said: " *The pesticide tests are fundamentally different*." *The ultimate goal in drug tests is to make people healthy, but the pesticide tests help to determine at what* ***levels*** *of exposure some "healthy people" become "****acutely****" sick. Further, the drug tests usually involve people who already are ill, while the pesticide tests seek "only" healthy adult subjects. Thus, how much risk healthy individuals should bear when there is not a clear benefit to the person? All of the rik is to the*

individul subjects, and all the benefts are to society or the companies producing these poisons.

Another issue is whether human pesticide studies are statistically valid?

An advisory member of EPA panel said that the **sample** in the 14 studies sent to EPA was **too small**. One examined 7 subjects, an another examined 50. That cannot help establish a no-effect levl, a standard below which no noticeable reaction. A study would need from **1,000 to 5,000 human participants** to be statistically correct!!

A **senior director** of scientific and regulatory policy for crop association (Washington) disagreed. "*The studies are valid*", he said, "*because they examine **enzyme function**, which varies in humans anyway. So finding response in a small number of human pesticide testers could be **translated** to the population at large*".It is also important that the testing subjects **volunteers**, and are **informed** of the **substance** they are taking, the **dosage**, and its **risks**.

The informed-consent form explains that the test involves chlorpyrifos, sketches its effects on the nervous system, outlines how the study will be conducted, and warns that there are 15 potential adverse reactions, including headache, dizzines, abdominal cramps, tremors, and tightness in the chest. It has also a pregnancy- related warning " Although animals studies indicate little or no risk in human, the possible side effects to a fetus or embryo are **unknown**."

The volunteers of **MDS Harris** study were 30 men and 30 women. More than one-third were 18 to 25 years- old; the rest in their late 20's to early 50's; most were nonsmokers. Volunteers were enlisted through ads in news papers and internet, *e.g*. EARN EXTRA MONEY, or MAKE A DIFFERENCE BY ASSISTING IN MEDICAL RESEARCH. Participants were given health screenings, and drug and alcohol tests to determine medical history and fitness. They were told that the material was registered insecticide. The main questions are:

1. How many sick/ill people/babies will be exposed to only the a.i.?
2. How can you "scientifically" ignore the dangers of the bulk of the formulation?

What is the definition of an adverse experience?

An adverse experince is defind as "**serious**" if it has, as its outcome, death, a life-threatening condition, inpatient

hospitalization or prolongation of existing hospitlzation, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or medical intervention to prevent such an outcome.

Ethical Principles for Safeguarding Human Subjects:

Over several decades , esteemed organizations have sought to provide ethical guidance for protecting human subjects in **medical** experimenation and **biomedical** research. The **Nuremberg Code in 1949** calls for " Fully-informed, voluntary consent by human subjects as the essential requisite for their enrollment in medical experimentaion, and for prohibitions on experimentation which is "**random**", "likely to cause unnecessary **suffering** or **death**", or which poses **riks** which exceed "the **humanitarian importance** of the problem to be solved."

These principles were amplified in 1964 by the World Medical Association in its "**Helsinki Declaration**", a **moral code of conduct** for medical researchers, recognizing that: medical research on humans may be done for various beneficient purposes:

1. Reseach for the **diagnostic** or **theraputic** benefit of a patient, and
2. Reseach done solely for **scientific purposes** "without implications of direct diagnostic or theraputic value" for the human subject involved.

Informed consent, and other relatively conventional principles of due care for patients, are enunciated for the former case. BUT, new precautionary principles are set forth for safeguarding human subjects in the 2nd category. The declaration provides that: "It is the duty of the physician to remain the protector of the life and health" of human subjects involved, to discontinue research which, if continued, would be harmful to the subjects, and not to allow **scientific** or **societal interests** to ever take precdence "over the well-being of the subject."

In 1979, **The National Commission for the Protection of Human Subject of Biomedical and Behavioal Research** (USA) issued **Belmont Report**, which provides the foundation for the protections now afforded human subjects in **gene therapy,** and other biomedical trials, by government agencies. According to the report, research programs and pojects must adhere to **three basic ethical principles**:

1. **Respect** for persons through full implimentation of informed consent procedures,
2. **beneficence** in research on humans by "maximizing possible benefits" while minimizing possible harms" and,
3. **justice** in the distribution of research benefits and burdens accross society.

Despite the thoughtful discussion of the three principles, the report concludes with "**permissive recommendations**." Prescriptions, prohibitions, and other strict limitations are **avoided**, and an ethically informed, but flexible decision process is propounded for researchers, to follow in designing, and conducting activities with human subjects. To avoid restrictions, the report **replaced** "*do not harm*" (avoided to use it) by "*with a qualitative balancing analysis*". "*…..avoiding harm requires learning **what is harmful**; and in the process of obtaining this information, persons my be exposed to risk of harm. Learning what in fact benefit may require exposing persons to risk. The problem posed is to decide when it is justifiable to seek certain beneits despite the risks involved, and when the benefis should be foregone because of the risk.* Thus, the report offers **morally-informed** , but **ultimately permssive guidance** to researchers, *i.e.* cost/benefit analysis, for determining protections afforded to human subjects. Only a few unavoidable limits on researcher discretion are expressed, *e.g.*

1. Brutal or inhumane treatment of human subjecs is never morally justified.
2. A higher level of justification is needed for enlisting "**vulnerable populaion** (*e.g.* children, prisoners) as human subjects.
3. Relevant risks and benefits **must** be thoroughly arrayed in the informed consent process.

Encouraged by the Belmont report, and other permissive rationales, including those articulated by **The National Bioethics Advisory Commission**, government regulators, and grant providers, indivdual researchers, and their organizations are now engaged in **authorized** clinical trials for new biotech products, including pesticides, despite their potential for harming the human subjects involved.

Failures of FDA:

FDA failed to enforce its own rules:

1. Failure to follow stopping rules presented by project protocols; *e.g*. if a single subject develops grade III or higher toxicity (5 subjects exhibited grade III toxicity).
2. Failure to exclude persons from the trial who did not meet subject selection criteria (4 of them)
3. Submitting misleading, and inaccurate information of adverse events, and modifying protocol-required test procedures without review and approval.
4. Failure to obtain informed consent by not revising documents.

Researchers responded with 691 adverse event reports, which they had not previously submitted

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5. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192, 23,192 (1979) (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Dept. of Health, Education and Welfare) [hereinafter The Belmont Report].

6.Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission, Exec. Order No. 12975, 60 Fed. Reg. 52,063 (Oct. 3, 1995).

7.ANDREW HALE ET AL., AFTER THE EVENT: FROM ACCIDENT TO ORGANIZATIONAL LEARNING (1997) (discussing risk analysis and risk management in hazardous industries); ANDREW HALE & MICHAEL BARAM, SAFETY MANAGEMENT: THE CHALLENGE OF CHANGE (1998).

8.Drugs are defined as "usually synthetic, organic compounds with defined structures and physical and chemical characteristics ... very stable and resistant to heat." Fishbein, supra note 7, at 8.

9.Phase I is closely monitored to establish an initial degree of confidence about safety of the product and dosage levels; Phase II is focused on efficacy for intended use as well as safety; and larger Phase III trials seek to gain statistical proof of safety and efficacy. Finally, a Phase IV trial may be conducted to confirm results and may extend, post-marketing, to study efficacy and safety in types of persons who were not subjects in the preceeding trials, such as children and the elderly.

10.Fishbein, supra note 7, at 13-16; O'Reilly, supra note 5, at 349-350; OFFICE OF THE INSPECTOR GENERAL, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, INSTITUTIONAL REVIEW BOARDS: PROMISING APPROACHES, No. OEI-01-97-00191 (1998) [hereinafter OIG REPORT]. According to O'Reilly and the OIG Report, clinical research consumes an estimated $4 billion annually, with three-fourths being company-sponsored and increasingly out-sourced to Contract Research Organizations (CRO's) and Study Management Organizations (SMO's) to reduce research costs. See id. CRO's/SMO's are small new companies that are widely-scattered and can be difficult to hold accountable to FDA procedures. See also Kurt Eichenwald & Gina Kolata, A Doctor's Drug Studies Turn into Fraud, N.Y. TIMES, May 17, 1999, at Al.

11."The reports submitted to the FDA are confidential and are not accessible to other investigators in the field as well. In general, the Freedom of Information Act requires Federal agencies to make their records available to the public upon request. However, this requirement does not apply to, among other things, "trade secrets and commercial or financial information that is obtained from a person and that is privileged or confidential." Under 18 U.S.C. 1905, it is a criminal offense for an officer or employee of ... any Federal department or agency to publish, divulge, disclose, or make known "in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, (or) processes ... of any person, firm, partnership, corporation or association." This [precludes FDA] from making the information public." Id. at 6-7; see also FDA Handbook, infra note 73.

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14. Human Subjects Protections in VA Medical Research: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Veterans Affairs, 106th Cong. (Sept. 28, 2000) (statement of Dr. Greg Koski, Director, Office for Human Research Protections, DHHS) at http://veterans.house.gov/hearings/schedule106/sept00/9-28-00/gkoski.htm.

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16. Sheryl Gay Stolberg, Experts Call for New Rules on Research, N.Y. TIMES, April 18, 2001, at A16 (regarding a proposed private accreditation system).

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